

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Open, non-comparative pilot study to provide access to treatment with investigational convalescent plasma and measure antibody levels in patients hospitalized with COVID-19

You are being invited to take part in a research study about a proposed treatment of COVID-19 with plasma collected from people who have had COVID-19 and have recovered.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

The purpose of this research is to provide access to treatment with investigational convalescent plasma in patients hospitalized with COVID-19 and to learn if treatment boosts your antibody levels. “Convalescent plasma”, or CP, refers to the liquid part of blood taken from people who have recovered from COVID-19 infection. CP does not contain blood cells but it does contain antibodies to SARS-CoV-2, the virus that causes COVID-19. Antibodies are part of your immune system, and it is thought that these antibodies may help fight SARS-COV-2 infection. You may be eligible for treatment with CP if you are currently hospitalized with a confirmed positive test for COVID-19 virus. Your participation in this research may include blood tests for pregnancy and blood type and a nasal swab test for COVID-19 if these have not already been done. If you are eligible, you will receive one unit (200 ml or about seven ounces) of CP, and you’ll have blood drawn for routine laboratory tests and virus antibody levels. Additional swabs will be taken from the front or back of your nose to monitor changes in the virus on the day of the transfusion and days 1, 3, 7, and 14. Your participation in this research will end when you leave the hospital.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

It is possible that you may benefit from plasma transfusion if the antibodies in the plasma help fight SARS-CoV-2 infection. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Convalescent plasma treatment is investigational and has not been proven to benefit COVID-19 patients. You may choose not to participate because plasma transfusion is accompanied by a risk, and it may not help you fight the virus. For a complete description of risks and alternate treatment/procedures, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Michelle Harkins of the University of New Mexico Health Sciences Center, Department of Internal Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is mharkins@salud.unm.edu or 505-272-4751.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Pacific Time (MPT), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version 1.0 April 29, 2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

The reasons you would not qualify for this study include being under 18 years of age, having a negative test for SARS-CoV-2 from nose swabs, inability for you or your legally authorized representative to provide consent, if you are female and are pregnant or breastfeeding, or you have a history of severe allergic reactions to blood or plasma infusions.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at UNMH. You will be evaluated up to six times during the study. Each of those visits will take 10-20 minutes, and the plasma infusion will take no more than four hours. The total amount of time you will be asked to volunteer for this study is about five hours during your hospitalization.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate, you will be asked about your symptoms, travel history, exposure to persons with COVID-19, medications before entering the hospital and your medical records and laboratory results will be reviewed in the electronic medical record in the hospital. If you do not have a positive test for COVID-19 at the time of screening, your nose or throat will be swabbed. If you are a female who could become pregnant, you will be given a pregnancy test. Once we have confirmed that you are eligible for the study, you will receive a 200 ml (about seven ounces) infusion of plasma that was collected from someone who has recovered from COVID-19.

Your blood pressure, pulse, breathing, and temperature will be checked just before, 10-20 minutes after starting the infusion, at the end of the infusion, and 30-60 minutes after the infusion. Before the infusion, and 1, 3, 7, and 14 days after the infusion (if you are still in the hospital), one tube of blood (5-7 ml or one to one and a half teaspoons) of blood will be drawn and your nose or throat will be swabbed. If you can't tolerate swabs to the back of the nose, only the front of your nose will be swabbed. You will also be asked about symptoms and be examined on each of these days. Treatment with plasma from persons who have recovered from COVID-19 is experimental, and everyone who participates in this research will receive this treatment.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Certain risks are associated with any transfusion of blood or plasma. It is possible that you might experience an allergic reaction to the plasma infusion that could include hives, itching and fever or even anaphylaxis, which is a severe, immediate and potentially life-threatening allergic reaction. Medical treatment will be provided to you in the event of an allergic reaction. Although it is uncommon, it is also possible for transmission of viruses (such as HIV, hepatitis B, hepatitis C and others) to occur through a plasma infusion. In order to minimize the risks of disease transmission, the person who donated the plasma you will receive will have fulfilled requirements for blood donation, and the plasma you receive will have been donated by a single, volunteer plasma donor. Other uncommon adverse reactions may include lung injury, overload of the heart, and hemolysis (breakage of blood cells). In event that these or any other adverse event occurs, you will receive medical treatment for them.

There is a risk that this experimental treatment could make your COVID-19 get worse, although this has not been observed in those who have already received this treatment. It is also possible that this treatment could improve your condition now but not protect you against getting COVID-19 again in the future.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

The drawing of blood with a needle from an arm vein usually causes mild pain (90%) and rarely causes a bruise (1%). There is a remote chance of fainting (less than 0.1%) and a very remote chance of infection (less than 0.01%).

There is a slight possibility that you may experience a loss of confidentiality regarding your medical records if you are enrolled in this study. In order to protect the privacy of your clinical information, the research team will take measures like restricting access to your records and using security passwords and locked cabinets for storing the data.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. You may or may not benefit from this treatment, but we are studying it because we believe it may help improve your condition. And, if you take part in this study, information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of New Mexico may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information of everyone who participated in the study. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

Deidentified information (without your name or other identifiers) with data collected from you in the research study will be stored in REDCap. REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, that as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons. You may be removed from the study if you are not able to follow the direction or they find that your participation in the study is more risk than benefit to you.

You may be removed from the study if:

- You are not able to follow the directions.
- The investigators find that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study, but involvement in this research will not prevent you from participation in other research studies unless prior convalescent plasma administration is not allowed by the other study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Michelle Harkins at 505-272-4751 immediately. Dr. Harkins will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking

part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Tests for research purposes are not meant to provide clinical information/diagnoses and cannot be used to make decisions about standard medical care.

The sample and/or information that you are donating will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

A description of this clinical trial will be available on [ClinicalTrials.gov](https://clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of 30 people to do so.

PROTECTED HEALTH INFORMATION OR SPECIMEN(S).

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes results of physical examinations, medical history, and results of blood tests, including antibody results.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw

your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Michelle Harkins, MD
MSC10 5550
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

If you become pregnant anytime during the study, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the FDA).

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr Harkins to inform her of your decision.
- Researchers may use and release your health information already collected for his research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject, or if applicable,

Date

**research subject's legal representative who may provide consent by phone*

Printed name of research subject

**If applicable, printed name of research subject's legal representative:* _____

**If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:*

I have witnessed the informed consent process. This informed consent form was verbally reviewed with the subject in addition to the HRRC approved short consent form and will act as the written summary of the discussion.

Witness (translator) printed name

Witness (translator) signature and date

I have witnessed the informed consent process that was conducted by phone call or by conference phone call. This informed consent form was verbally reviewed with the subject or their LAR.

Impartial Witness to phone consent printed name

Impartial Witness to phone consent signature and date

Printed name of [authorized] person obtaining
informed consent/HIPAA Authorization

Date

Signature of [authorized] person obtaining informed consent/HIPAA Authorization